

## REMARKS

### I. Amendment

Reconsideration of rejections in the Application is respectfully requested. Upon entry of the foregoing amendment, claims 9-17, 29-38, 47, 49, 51-55, 57 and 62-70 will be pending. Claims 9-17, 29-38, 47, 49, 51-55, 57 and 62-64 stand rejected. Claims 9, 16, 38 and 54 are amended. New claims 65-70 are added.

Applicant respectfully requests entry of the above amendment and submits that the amendment does not introduce new matter. Support for the amendment to the claims and for the new claims can be found throughout the specification (considered as a whole) and in the claims as originally filed. In particular, support for the amendment to claim 9 can be found, *inter alia*, in claim 9 as originally filed and in the specification at page 5, lines 28-30. Support for the amendment to claims 16 and 38 can be found, *inter alia*, in the claims as originally filed. Support for the amendment to claim 54 can be found, *inter alia*, in claim 54 as originally filed and in the specification at page 5, lines 28-30. Support for new claims 65 and 66 can be found, *inter alia*, in the specification at page 4, lines 30-34. Support for new claims 67 and 68 can be found, *inter alia*, in the specification at page 5, lines 28-30. Support for new claim 69 can be found, *inter alia*, in the specification at page 5, lines 32-33. Support for new claim 70, can be found, *inter alia*, at page 8, line 30 to page 9, line 7 of the specification.

Based on the above amendments and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding rejections and that the rejections be withdrawn.

### II. Claim Rejections

Claims 9-17, 29-38, 47, 49, 51-55, 57 and 62-64 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Russian Patent Application No. RU 2,148,957, in the name of Sknar *et al.* ("the '957 application"), in view of U.S. Patent No. 6,486,213, issued to Chen *et al.* ("the '213 patent"). Claims 9-15, 17, 29-38, 47 and 49 are provisionally rejected under obviousness-type double patenting as being unpatentable

over claims 1, 2, 5, 7-12 and 44-50 of copending U.S. Application No. 09/938,670 ("the '670 application") (published, according to the Office Action, as US 2002/0064512).

Rejections under 35 U.S.C. § 103(a)

It was asserted in the Office Action that the '957 application discloses a method of treating vesicoureteral reflux by injecting a polyacrylamide hydrogel, into the ostium ureteris of the ureter. It was acknowledged in the Office Action that Applicant's claim 9 recites the complex viscosity of its hydrogel of about 9 to 90 Pas. Regarding the claimed viscosity, it was asserted that the hydrogel of the '957 application has a level of viscosity, since the hydrogels of the prior art and Applicant's claims are injected. It was also asserted that the '213 patent discloses a hydrogel formulation that may be administered in the form of a suspension and that is prepared from acrylamide and methylene-bis-acrylamide. It was therefore asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and inject an acrylamide hydrogel formed from acrylamide and methylene-bis-acrylamide into the ostium ureteris of a ureter. It was further asserted that a person of ordinary skill would have been motivated to make the acrylamide and methylene-bis-acrylamide in such ratios to produce the desired cross-linked hydrogel for effective treatment of vesicoureteral reflux. See Office Action, pp. 2-4. Applicant respectfully traverses these rejections.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure.

M.P.E.P. § 2142 at 2100-128.

Initially, there is no suggestion or motivation to combine the '957 application with the '213 patent. The '957 application discloses a method of treating vesicouretral reflux ("VUR") by injecting a polyacrylamide hydrogel into the ureter (see Abstract and the first paragraph under "Description") whereas the '213 patent discloses copolymers for the delivery of a drug by topical application. See column 1, lines 13-17. There is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the two very distinct products. No basis in the references nor in the knowledge available to one of ordinary skill in the art was identified in the Office Action that the suggestion or motivation exists.

Moreover, even if one of ordinary skill in the art were motivated to combine the '957 application with the '213 patent, there would be no reasonable expectation of success for making the claimed invention. According to the '957 application, the polyacrylamide gel "Interfall" is "mounted on a special device of the 'gun' type and a small amount of the gel is extruded". See page 8, third paragraph under "Detailed description of the method and examples of a particular embodiment." The hydrogel of the claimed invention, however, has the claimed complex viscosity that allows it to be injected manually, thereby providing much greater control over the use of the hydrogel. The polymer of the claimed invention is advantageous over the prior art in that it is easier to inject and manipulate manually while, surprisingly, it is also highly elastic, which provides resistance in conduits, to treat incontinence. The claimed polymer has unique properties of being sufficiently "fluid" to be manually injectable and yet sufficiently "resistant" to provide bulking in cases of incontinence. Claims 9 and 54, from which all other claims depend, have been amended to claim the elasticity of the polymer used to treat incontinence. The topically applied copolymer of the '213 patent also does not have this unique combination of properties as defined in Applicant's claims. Therefore no combination of the '957 application and the '213 patent, nor any modification to such combination reasonably suggested by the prior art, would be expected to successfully obtain the claimed invention.

Furthermore, the '957 application and the '213 patent do not teach or suggest all the limitations of the claimed invention. First, independent claims 9 and 54 have been amended so they relate to treating incontinence. Neither the '957 application nor the '213 patent disclose a method for treating incontinence.

Second, the claimed invention method uses a polymer prepared by combining acrylamide and a cross-linking agent, but neither the '957 application, the '213 patent, nor any combination of the two teach or suggest this limitation. As stated by the Examiner, the '957 application "does not specifically disclose the reactants producing the acrylamide hydrogel." Office Action, page 3. This deficiency is not corrected by combining it with the '213 patent. The '213 patent describes a two-component block or graft co-polymer of pH-sensitive polymer and a temperature-sensitive polymer. See column 7, lines 52-54. The pH-sensitive polymer component may be cross-linked using methylene-bis-acrylamide, but the pH-sensitive polymer component does not comprise acrylamide. See column 20, lines 14-21. The pH-sensitive polymer may be, for example, derived from carboxylic acids or an amino- or phosphate-containing polymer. See column 14, line 56 to column 16, line 10. Polyacrylamide may be used as the temperature-sensitive polymer, but there is no disclosure of cross-linking the polyacrylamide. See column 12, line 16 to column 14, line 55. Therefore, the '213 patent is also silent as to combining acrylamide and a cross-linking agent, specifically methylene-bis-acrylamide. Because neither the '957 application nor the '213 patent disclose the claimed polymer, no combination of the two references could suggest or teach the limitation.

Third, hydrogel of the claimed invention has less than 50 ppm monomeric units. Although the disclosure of the '957 application states that there were "no complaints" after 3-6 months and that "postoperative complications were not observed in any case" (see Examples 1-3, pages 9-11), one of ordinary skill in the art was aware that the "Interfall" product discussed was known to cause complications, namely inflammation, pain, and infections, when used clinically. This was eventually attributed to the relatively high content of monomers in the Interfall product. The claimed invention, on

the other hand, limits the monomer content to less than 50 ppm. As of the filing date, the complications associated with the Interfall product were not known to persons skilled in the art to be attributable to the monomer content - the polymer was suspected as being unsafe in itself. The '213 patent also does not teach or suggest the limitation of monomers in the polymer of the claimed invention, and therefore, any combination of the two references does not suggest or teach this limitation.

Finally, as previously discussed, neither the '957 application, the '213 patent, nor any combination thereof discloses the combined complex viscosity and elasticity module of the claimed invention.

Claims 9-17, 29-38, 47, 49, 51-55, 57 and 62-64 are not obvious over the '957 application in view of the '213 patent because one of ordinary skill in the art would not be motivated to modify or combine the '957 application and the '213 patent to obtain the claimed invention. Even if one considered doing so, there would be no reasonable expectation of successfully obtaining the claimed invention, and moreover, all of the limitations of the claims would not be met. Therefore, Applicant respectfully requests that the Examiner reconsider the rejection of claims 9-17, 29-38, 47, 49, 51-55, 57 and 62-64 under 35 U.S.C. § 103(a) and that the rejection be withdrawn.

#### Double Patenting

Claims 9-15, 17, 29-38, 47 and 49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7-12 and 44-50 of the '670 application.

Applicant acknowledges the provisional obviousness-type double patenting rejection but requests that this rejection be held in abeyance until prosecution of at least of the present application or the '670 application is closed.

#### **III. Request for Interview**

In the event any outstanding issues remain after reconsideration of the rejections, Applicant would appreciate a telephone call to Applicant's undersigned

representative so that a telephonic interview may be scheduled to resolve such issues in an expeditious manner.

#### **IV. Consideration of References**

On the copy of Form PTO-1449 submitted with the Information Disclosure Statement on July 26, 2005 ("IDS") (attached to the Office Action), the Examiner crossed-out Document Nos. 1-4 and stated that the references were duplicative of those submitted on June 22, 2005. However, as stated in the IDS, Document No. 1 was the full text of GB 2,114,578, only the Abstract of which was previously submitted on June 22, 2005. In addition, Document Nos. 2-4 submitted on July 26, 2005 were complete translations of the incomplete translations previously submitted on June 22, 2005.

Applicant resubmits, herewith, a copy of the Form PTO-1449 submitted on July 26, 2005 and respectfully requests the Examiner to consider the full text and translations of the references cited therein and return a copy of the enclosed Form PTO-1449 with the Examiner's initials in the left column in accordance with M.P.E.P. § 609 to indicate on the record that the full text and translations were considered.

#### **CONCLUSION**

For at least the reasons stated above, claims 9-17, 29-38, 47, 49, 51-55, 57 and 62-70 are in condition for allowance. Accordingly, Applicant respectfully requests that the Application be reconsidered, allowed and passed to issue.

This Amendment is filed within the three-month shortened statutory period for reply. Therefore, it is believed that no fees are due. However, in the event it is determined by the PTO that fees are due, the Commissioner is authorized to charge such fees to the undersigned's Deposit Account No. 50-0206.

In re U.S. Patent Application of Jens PETERSEN  
Serial No.: 09/938,667 Filing Date: August 27, 2001  
Title: POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE AND  
VESICoureTAL REFLUX

Respectfully submitted,

Date: December 14, 2005

By: Victoria A. Silcott  
Stanislaus Aksman  
Registration No. 28,562

Victoria A. Silcott  
Registration No. 57,443

**HUNTON & WILLIAMS, LLP**  
Intellectual Property Department  
1900 K Street, N.W.  
Suite 1200  
Washington, DC 20006-1109  
Telephone: (202) 955-1926  
Facsimile: (202) 778-2201